



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



MAR 30 2006

TO: Phyllis Johnson
Director, Beltsville Agricultural Research Center
Agricultural Research Service

FROM: Raymond G. Poland /s/
Acting Director, Planning and Special Projects
Office of Inspector General

SUBJECT: Office of Inspector General Site Visit to the Agricultural Research Service
Produce Quality and Safety Laboratory

This memorandum provides the results of the Office of Inspector General's (OIG) site visit to the Agricultural Research Service's (ARS) Produce Quality and Safety Laboratory (PQSL) on December 15, 2005. The purpose of the OIG visit was twofold. First, we wanted to verify that ARS had implemented recommendations that the Centers for Disease Control and Prevention (CDC) had made in a July 20, 2004, trip report. The subject of the trip report was an investigation of a dual infection with *Escherichia coli* O157:H7 and *Salmonella* serotype Choleraesuis var. Kunzendorf in a research laboratory worker. Second, we wanted to validate ARS' implementation of the related corrective actions cited in its letter to OIG dated August 17, 2005. Generally, we found that ARS had responded satisfactorily to CDC's recommendations. However, we noted that ARS could take some additional actions to enhance the safety of the laboratory staff. We are summarizing the findings and resulting recommendations from our site visit in this memorandum. The site visit was conducted in accordance with the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency Quality Standards for Inspections (January 2005) and OIG's policies and procedures.

Summary of the CDC Investigation Findings and Recommendations

Among the recommendations made by CDC are the following:

- Require clear documentation of personnel using Biosafety Level 2 (BSL-2) agents
- Post BSL-2 status on doors and specified pathogens in use
- Ensure all laboratory staff receive appropriate training
- Maintain institutional laundry facilities or enforce a disposable laboratory coat policy
- Use a phenolic or quaternary ammonium compound as standard disinfectant
- Further restrict physical access to the BSL-2 laboratory
- Obtain a baseline serum sample for all employees working with BSL-2 agents.

OIG's site visit to PQSL

The OIG site visit consisted of the following:

- Interviews with various ARS officials, including the Deputy Director of the Beltsville Agricultural Research Center, the Research Leader of the PQSL, and the Area Safety and Health Manager, Safety Occupational Health and Environmental Staff
- Review of the PQSL Safety Training presentation for new employees and related materials
- Tour of the PQSL facilities.

The interviews concerned the implementation of laboratory safety practices and procedures as recommended in the CDC report. The interviews focused on such practices and procedures including, but not limited to, how spills are reported, how new employees are trained, and how management monitors compliance with the established safety rules specific to the PQSL.

Prior to the site visit, OIG reviewed all of the CDC report recommendations. During the site visit, OIG verified implementation of CDC recommendations. OIG noted the presence and condition of biosafety-related signage,¹ physical security measures, maintenance of biosafety cabinets, availability of appropriate disinfectants and personal safety equipment, and lab sink location and configuration.

OIG Findings

In summary, OIG found that where feasible, ARS had implemented the CDC recommendations along with other safety enhancements, including the installation of hands-free sinks, in close proximity to the biosafety cabinets. ARS decided, and OIG agrees, that one of the CDC recommendations was not feasible given the constraints of the environment. Specifically, CDC had recommended modifications be made to the laboratory doors to further enhance physical security. ARS decided, and OIG agrees, that such an enhancement would impede the movement of the laboratory workers and serve to isolate them from their colleagues. One exception to ARS' implementation of the CDC recommendations, which OIG questions, is the recommendation to collect baseline serum samples from employees working in the PQSL. ARS officials stated that such a collection would be done under the Occupational Medical Surveillance Program (OMSP). Currently, participation in this program is voluntary under ARS policy.

¹ OIG noted one instance of a strain present in a laboratory refrigerator that was not listed on the door sign listing hazardous microorganisms. This was pointed out to ARS officials for corrective action.

OIG Recommendation

OIG recommends that the agency investigate the possibility of making participation in the OMSP mandatory. As OIG recognizes that mandatory participation in the OMSP could be complicated by privacy concerns, we recommend consulting with the Department of Agriculture's Office of General Counsel regarding implementation of any such mandatory participation program. If participation in the OMSP cannot be mandatory, OIG recommends that ARS consider implementing an educational program for its employees who work with biohazardous agents, to fully apprise them of the benefits of participating in such a program.

Please furnish a reply within 60 days describing the corrective actions taken or planned and the time frames for implementing this recommendation. As this is not an OIG audit report, the Office of the Chief Financial Officer will not be involved in the resolution of the recommendation.

OIG is satisfied with the agency's implementation of the CDC recommendations and considers our site review to be complete. If you have any additional questions regarding the OIG site visit, you may direct them to: Susan J. Carlson, Ph.D., 202-720-4100, sjcarlson@oig.usda.gov.



United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

May 30, 2006

SUBJECT: Office of Inspector General Site Visit to the Agricultural Research Service
Produce Quality and Safety Laboratory

TO: Raymond G. Poland
Acting Director, Planning and Special Projects
Office of Inspector General

FROM: Phyllis E. Johnson
Director

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This is in response to your memorandum dated March 30, 2006, concerning the report of the Office of Inspector General (OIG) site visit to the Produce Quality and Safety Laboratory (PQSL) at Beltsville Agricultural Research Center on December 15, 2005.

We are pleased that the OIG is satisfied with our implementation of the recommendations of the Centers for Disease Control and Prevention (CDC) in the CDC's July 20, 2004, trip report. The one exception noted in the OIG report that we are to pursue is mandatory participation in the Occupational Medical Surveillance Program (OMSP), based on the CDC recommendation to collect baseline serum samples from employees working in the PQSL. It is the recommendation of the OIG that we investigate this possibility and consult with the Department of Agriculture's Office of the General Counsel (OGC) regarding implementation of any such mandatory program.

We are consulting with OGC on the possibility of making participation in the OMSP mandatory for the purpose of obtaining baseline serum samples. Participation in the OMSP is already mandatory by regulation for some employees, such as those who are certified pesticide applicators and must participate in a respiratory protection program as mandated by the Occupational Safety and Health Administration, and whose cholinesterase levels are monitored.

As recommended by the OIG, we have an educational program apprising employees of the benefits of participating in the OMSP, particularly those who work with biohazardous agents. All employees are informed of the program when they are hired, and are



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encouraged during biosafety and other training courses. They are also reminded of the program as appropriate during review of research protocols, lab inspections, and meetings with laboratory personnel.

If you have any questions regarding this response, you may direct them to me, or our Area Safety and Health Manager, David Prevar, 301-504-5557, prevard@ba.ars.usda.gov.

cc:

Bill Conway, PQSL

Kenneth Gross, PQSL

David Prevar, SOHES